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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,924	01/14/2002	Sylvaine Cases	UCAL-240CIP	4706

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BOZICEVIC, FIELD & FRANCIS LLP
200 MIDDLEFIELD RD
SUITE 200
MENLO PARK, CA 94025

EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,924	CASES ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *3-6 and 11-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7-10 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment of the specification and claims 1, 2, 7 and 10 and the addition of new claims 24-27, in the paper of 11/12/2003, is acknowledged. Claims 1-27 are still at issue and are present for examination.

Applicants' arguments filed on 11/12/2003, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 3, 4-6 and 11-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

Claim 25 is objected to because of the following informalities:

Claim 25 recites "monoacylglycerol transferase activity". This recitation is interpreted as "monoacylglycerol acyltransferase activity", as there is no support for "monoacylglycerol transferase activity".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 7-10, 24-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide comprising a nucleic acid sequence of SEQ ID NO: 3, wherein said polynucleotide encodes a polypeptide with DGAT activity, does not reasonably provide enablement for any polynucleotide which encodes a polypeptide that exhibits diacylglycerol acyltransferase activity wherein said polynucleotide has a mere 90% identity to SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 1, 2 and 7-10. In response to this rejection applicants have amended claims 1, 2, 7 and 10 and added new claims 24-27 and traverse this rejection as it applies to these newly amended claims.

Applicants traverse this rejection on the basis that the specification provides ample description of how to make and use a polynucleotide as recited in claim 1. In so doing applicants submit that the specification provides two polynucleotides that comprise a nucleotide sequence that encode a polypeptide that exhibits monoacylglycerol and/or diacylglycerol acyltransferase activity and that comprise a nucleotide sequence that has at least 90% nucleotide sequence identity to SEQ ID NO: 03 (i.e. SEQ ID NO: 1 and SEQ ID NO: 3). Applicants is reminded that the rejected claims are drawn to any and all polynucleotides which encode a polypeptide with monoacylglycerol and/or diacylglycerol acyltransferase activity and that are 90%

identical to SEQ ID NO: 3, a genus of molecules including a number of species far in excess of the two disclosed species.

Applicants further argue that the amended claims are enabled by addressing each of the Wands factors individually (In re Wands (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)).

With respect to factor (1), the quantity of experimentation necessary, applicants submit that while the fact that the experimentation may be complex, this alone does not necessarily make it undue. With respect to factor (2) the amount of direction or guidance presented, applicants submit that they have provide two polynucleotides encompassed by the claimed genus and applicants specification provides a description of how to measure monoacylglycerol and/or diacylglycerol acyltransferase activity. Applicants submit that they have not provided and they are not required for compliance with the enablement, working examples. Applicants further submit that the level of skill of those in the art is high and that while the art may be unpredictable, the specification does not have to disclose every species of a genus.

While applicants specification teaches the complete nucleotide sequences of SEQ ID NOs:1 and 3 and methods for producing variants of a disclosed sequence are within the skill of the ordinary artisan, applicants argument is not persuasive because while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., encoding a protein with monoacylglycerol and/or diacylglycerol acyltransferase activity) requires that one of ordinary skill in the art know

or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of **guidance** with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As previously stated the specification does not establish: (A) regions of the protein structure which may be modified without effecting diacylglycerol transferase activity; (B) the general tolerance of diacylglycerol transferases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a diacylglycerol transferase with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any polynucleotide having a mere 90% sequence identity to SEQ ID NO: 3 and encoding a polypeptide with monoacylglycerol and/or diacylglycerol transferase activity. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired

biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7-10, 26 and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Baker et al. (WO 00/12708, March 2000, See IDS ref).

The rejection is stated in the previous office action. In response to this rejection applicants have amended claims 1, 2, 7 and 10 and added new claims 26 and 27 and argue the rejection as it applies to the amended claims.

As previously stated, Baker et al. teach a number of human polynucleotides which encode membrane-bound proteins including that polynucleotide shown in Figure 163, which encodes the transmembrane protein pro1433 shown in Figure 164. The polynucleotide taught by Baker et al. is greater than 89% identical over the entire length of instantly disclosed SEQ ID NO: 3. In fact an alignment of the sequence taught by Baker et al. and that of the instantly disclosed SEQ ID NO: 3 shows an alignment of 89.7% identity. As applicants claim recites the percent identity merely to those digits to

the left of the decimal point, conversion of the percent identity of the polynucleotide taught by Baker et al. is 90%, as it is common practice to round any digit above 5 up.

Further the protein encoded by the polynucleotide taught by Baker et al. has a best local similarity score of greater then 93% (i.e. 93.8%) relative to the amino acid sequence of SEQ ID NO: 4.

Thus Baker et al. anticipates claims 1, 2, 7-10, 26 and 27.

Conclusion

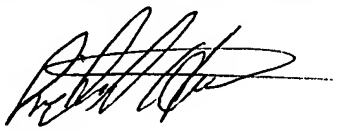
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
2/18/2004